# The Role of Simulation in Aortic Endografting

How this tool can be used effectively to train the next generation of vascular clinicians.

BY ALAN B. LUMSDEN, MD; JEAN BISMUTH, MD; AND MICHAEL A. DONOVAN, BS

ndovascular training for vascular surgeons began in the mid 1990s, and at that time, the use of glass and plastic flow models was considered "state of the art." The Society of Clinical Vascular Surgery, under the direction of Dr. Kim Hodgson, was first to run what were considered cutting-edge, hands-on courses using these models and portable C-arms to teach basic catheter and wire skills. Now considered rudimentary, these models served to educate a generation of vascular trainees. Supplemented by mini-fellowships and device-specific multiday courses, the endovascular transformation of vascular surgery had begun, and these modules all played an important role. Fast-forward 15 years, and one can reasonably ask the question, "Where are we now?" An increased number of devices, more complex devices, shortened resident work hours, and competition from multiple specialties are all factors that confound endovascular training. Endografts represent some of the most complex devices ever developed for the endovascular space, and with the emergence of branched vessels, they also represent significant training challenges. This article addresses the role of simulation for endograft training.

# **DEFINITION OF MEDICAL SIMULATION**

*Medical simulation* is defined as "a person, device, or set of conditions that attempts to present (education and) evaluation problems authentically." Multiple types of simulator exist, each with their particular role. The students or trainees are required to respond to the simulated problems as they would under natural circumstances. Frequently, the trainees receive performance feedback as if they were involved in a real situation.<sup>1,2</sup> One elemental question remains: how much realism is actually necessary? Some of the common characteristics of most simulation technologies are:

- Cues and consequences that are very close to reality
- Ability to simulate complex situations
- Limitations in technology (eg, the endosimulator's inability to learn, reliability of haptics)
- · High costs

Varying formats that can be either interactive or individualistic, inanimate (ie, anatomical model), or computer-based (ie, endosimulators).

The Agency for Healthcare Research and Quality report from 2007 essentially supports the effectiveness of simulation training "especially for psychomotor skills (eg, procedures) and communication skills." However, this support is limited by data that are weak due to the small number of suitable trials and the lack of quantitative data.

# SIMULATION AND AORTIC DISEASE

Interestingly, we now see a move back to the models and flow circuit-based simulation, albeit in a much more sophisticated environment compared to the models of 1995. This has been pioneered by a group of European surgeons working with the European Society for Vascular Surgery to create complex models that can be used for both endovascular training and for practicing and measuring technical capabilities for open aortic repair (Figure 1). Taught annually in Pontresina, Switzerland, students under the supervision of



Figure 1. Pontresina abdominal aortic training for open repair of an aortic aneurysm. A flow pump below the module provides pulsatile flow. Actual surgical retractors and instruments must be used. Aneurysms are replaceable, and assistance is necessary.

senior surgeons practice open aneurysm repair in a flow model environment. The European Board of Vascular Surgery has developed a validated method of testing vascular surgery skills that is now required for their board certification.<sup>4</sup> No such program exists in the United States or in other parts of the world, although fledgling programs are beginning to quantitate the value of simulation in training.<sup>5,6</sup> Introducing this type of training to the United States and to the international surgery community will help to standardize the workforce, increase the level of expertise among cardiovascular surgeons, and potentially shorten the learning curve for developing these skills. The American Board of Internal Medicine has developed Medical Knowledge Modules, which include interventional cardiology simulation. This is a pilot program in which simulation permits the candidate to accrue points toward maintenance of certification.

The Pontresina endovascular tower (Figure 2) permits groin puncture and device delivery into flowing glass models under video control (replacing C-arms) in a radiation-free environment. The real advantage of these towers is that actual stent grafts are delivered and deployed, providing the trainee with the tactile feedback associated with delivery of different types of devices. Also, adjustable pulsatile flow gives the model an even greater sense of realism.

One real challenge in the evolution of a true simulation experience for aortic endografts has been the disconnect between simulation companies and the device manufacturers. The device companies have long been uncertain about the real value in simulation and consequently have been reluctant to invest in the development of simulation modules. With fewer cash reserves, the simulation companies have not had the resources or desire to develop these simulated aortic environments alone. Both believe that hospitals should appreciate the potential role of simulation in credentialing and recredentialing. But, to date, no matrices exist by which hospitals can use these expensive simulators to credential, refuse credentialing, or remove credentialing for physicians based on their performance in aortic simulation or in any other endovascular models.

This complex situation of who owns the simulator versus who owns the training module led to a bitter experience for our institution in which we leased and housed the simulator but were denied access to the most recently developed and



Figure 2. The endovascular tower has groin vessels that must be accessed using standard techniques. This is a radiation-free environment in which a C-arm is replaced by a mobile video camera that can be panned in a cranial-caudal direction or right and left anterior oblique direction to visualize devices tracked up through the transparent glass model.

most exciting modules. This led to a situation in which the standard modules were rapidly used and little additional value in the simulator was perceived. We learned that we needed continuously updated material of increasing complexity with built-in complications.

Consequently, it is only recently that aortic endograft simulation models have evolved. Medtronic, Inc. (Minneapolis, MN) first developed a thoracic simulation environment (Figure 3) in partnership with Medical Simulation Corporation (Denver, CO) for deployment of their Talent endograft. Interestingly, they also developed a dissection module, which would have been of immense value but was unavailable for United States physicians because this was an "off-label" indication for their device.

The absurdity of this is obvious. Module development is dependent on a device company that can only permit use of their module if it is in line with US Food and Drug Administration-approved indications for that device. Consequently, despite the fact that most physicians now believe that

stent grafting is the first-line intervention for complicated type B dissections, they were denied access (on regulatory grounds) to the one training system that could have benefited them and such patients.

W. L. Gore & Associates (Flagstaff, AZ) has partnered with Simbionix Ltd. (Cleveland, OH) to develop an abdominal aortic aneurysm simulation platform for the EXCLUDER Device (Figure 4). This was created in conjunction with coauthor Dr. Jean Bismuth. One potential advantage of the Simbionix platform is the ease of performing patient-specific simulation. Computed tomography (CT) scans in DICOM format can be loaded into the simulator to provide a "patient-like" simulation. Why the distinction? Basically, these simulation scenarios are created from a contrastenhanced CT scan, whereas interventionists deploy devices using angiography. Not only do we deploy the devices using real-time angiography, but the device itself deforms the anatomy, and these device-tissue interactions are not yet modeled in simulation scenarios. Consequently, most simulation companies are not yet ready to claim the true fidelity of patient-specific scenarios. This claim may need a clinical trial approved by the US Food and Drug Administration to demonstrate true fidelity before it can be made. Nevertheless, we strongly believe that the capability of simulators to continuously modify the scenarios is an absolute



Figure 3. Dr. Denton Cooley evaluating the Medtronic module for placement of thoracic endografts (A). The simulator forces the physician to size the aneurysm and select the appropriate lengths and diameters of the devices to be deployed (B).

prerequisite to provide value in simulation. The real value is in simulating tomorrow's case today, provided the clinician is not lured into performing the procedure because of its ease of use in a simulation environment.

Although there is clearly a difference between angiographic guidance and CT guidance, those margins are becoming increasingly hard to distinguish. Modern hybrid rooms all permit the acquisition of CT scans using the image detector. Three-dimensional (3D) reconstruction and 3D overlay are increasingly being used as guidance systems (Figure 5). Consequently, the lines of distinction between CT angiography-based simulation and the intraprocedural imaging modality are rapidly being blurred.

Management of complications, especially device-specific complications and unusual clinical scenarios, is yet another mandatory component in simulation evolution. Indeed, rehearsing these seldom-experienced situations could be one of the most important assets of simulation.

# METHODIST INSTITUTE FOR TECHNOLOGY AND EDUCATION

Depending on the ultimate goals of the individual training center, the infrastructure can clearly vary, but either way, a significant investment is necessary. Having perceived a huge void, a significant investment was made in the Methodist Institute for Technology and Education in Houston, Texas, which has trained more than 2,500 health care professionals across 16 different specialties since 2007. The mission of the training center at the Methodist Hospital is to serve as an educational resource for practicing health care professionals seeking to maintain excellent clinical skills and acquire new ones. Like many other training facilities, it is intended to improve patient safety through educational

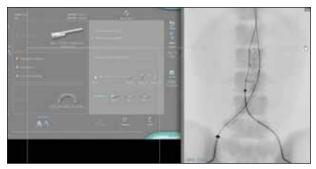


Figure 4. Simbionix-based Gore module for deployment of the EXCLUDER abdominal aortic endograft. In this situation, the main body has been deployed. The operator must now catheterize the contralateral gate and deploy the contralateral limb.

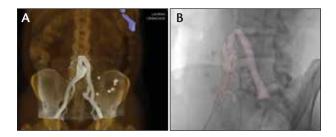


Figure 5. A 3D reconstruction of a rotational angiogram fused with an imported, previously acquired CT scan (A). The 3D overlay is then used to guide stent graft placement in the iliac aneurysm (B).

pursuits and conduct research on skills acquisition and technological development. The DeBakey Institute for Cardiovascular Education and Training has now been developed to support cardiovascular education, with a focus on aortic endografting. This will be launched within our extensive hands-on experience at the upcoming Total Endovascular Aorta II meeting in March 2011.

# CONCLUSION

Given the quickly evolving world of endovascular therapeutics, it will be necessary for health care professionals to train on new devices and/or develop new techniques. Simulation is able to fill the education gap and likely improve physician confidence and patient outcomes. Although simulation for aortic endografting has lagged behind endovascular simulation in general, simulated environments for percutaneous aortic valves to thoracic endografts to abdominal aortic endografts are available. The expansion of simulated cases, the ability to develop patient-like modules, and the development of various simulated complications will greatly increase their utility.

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Alan B. Lumsden, MD, is with the Methodist DeBakey Heart & Vascular Center, The Methodist Hospital in Houston, Texas. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein. Dr. Lumsden may be reached at ablumsden@tmhs.org.

Jean Bismuth, MD, is with the Methodist DeBakey Heart & Vascular Center, The Methodist Hospital in Houston, Texas. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein.

Michael A. Donovan, BS, is with the Methodist DeBakey Heart & Vascular Center, The Methodist Hospital in Houston, Texas. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein.

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